

This listing of the claims replaces all prior versions in the application.

Listing of Claims:

1. (Currently Amended) An implantable prosthesis of shape generally similar to that of a spinal intervertebral disc, comprised of a biocompatible elastomer ~~with a compressive modulus of elasticity less than about 100 megaPascals,~~ with an ultimate strength in tension generally greater than about 100 kiloPascals, that exhibits the flexibility to allow at least 2 degrees of rotation between the top and bottom faces with torsions of at least ~~about~~ 0.01 N-m without failing.
2. (Currently Amended) A prosthesis according to Claim 1 wherein the device has ~~[[an]]~~ a ultimate compressive strength sufficient to withstand a compressive load greater than 1 MegaPascals.
3. (Currently Amended) A prosthesis according to Claim 1 wherein the ~~material used for the~~ device has an ultimate strength in tension and compression which is greater than ~~about~~ 5-1 MPa.
4. (Currently Amended) A prosthesis according to Claim 1 wherein the device is ~~made of~~ a molded freeze-thaw body formed of a single solid elastomeric cryogel material formed from a mold formulation of polyvinyl alcohol (PVA) powder in an amount of between about 25% to 50% by weight and solvent.
5. (Currently Amended) A prosthesis according to Claim 1 wherein the elastomer has a compressive ~~modulus of elasticity of~~ strength at least ~~about~~ 1.0 MPa.
6. (Currently Amended) A prosthesis according to Claim 1 wherein the elastomer has a compressive strength of ~~modulus of elasticity less than 20~~ at least 10 MPa.

7. (Currently Amended) A prosthesis according to Claim 1 wherein the device has a compressive modulus of elasticity that is between 0.1 MPa and less than about 10 MPa and greater than about 200 KPa.

8. (Withdrawn) A prosthesis according to Claim 1 wherein the elastomer has a ~~compressive modulus of elasticity~~ that is not constant or that is anisotropic.

9. (Currently Amended) A prosthesis according to Claim 1 wherein the delivered size of the prosthesis can passively expand ~~at least 5%~~ in at least one dimension over one day, in saline.

10. (Withdrawn) A prosthesis according to Claim 1 wherein the delivered size of the prosthesis can expand at least 5% ~~[[50%]]~~ in at least one dimension in vivo without injection of material.

11. (Withdrawn) A prosthesis according to Claim 1 wherein the delivered size of the prosthesis can expand at least 20% over one day in at least one dimension in vivo and can generate a cranial-caudal force of greater than ~~about~~ 1 Newton.

12. (Withdrawn) A prosthesis according to Claim 1 wherein the delivered size of the prosthesis can expand at least 100% by a combination of springs and elastomeric components.

13. (Previously Presented) A prosthesis according to Claim 1 the elastomer defines an exposed surface that is modified to provide specific surface characteristics.

14. (Original) A prosthesis according to Claim 13 wherein the surface characteristics are physically or biochemically modified to provide enhanced adhesion to a vertebral body.

15. (Previously Presented) A prosthesis according to Claim 13 wherein the surface includes a fabric.

16. (Currently Amended) A prosthesis according to Claim 13 wherein the surface includes a ~~metal solid or~~ mesh.

17. (Previously Presented) A prosthesis according to Claim 13 wherein the surface includes a porous structure with undercuts.

18. (Previously Presented) A prosthesis according to Claim 13 wherein the surface includes a rough surface greater than 5 nanometers.

19. (Previously Presented) A prosthesis according to Claim 13 wherein the surface includes a bioactive molecule.

20. (Currently Amended) A prosthesis according to Claim 1 wherein the top and bottom surfaces have surface characteristics that ~~of the prosthesis~~ allow cellular ingrowth.

21. (Previously Presented) A prosthesis according to Claim 1 wherein surface characteristics of the elastomer are biochemically modified to provide enhanced water transport.

22. (Previously Presented) A prosthesis according to Claim 1 wherein surface characteristics of the prosthesis are physically modified to provide enhanced chemical transport.

23. (Currently Amended) A prosthesis according to Claim 1 wherein the device is a unitary non-articulating ~~plateless~~ body devoid of endplates made of a single solid elastomer

~~with a compressive modulus of elasticity between about 0.2 and 10 megaPascals with tab~~
extensions for fixation to the adjacent vertebral bodies.

24. (Currently Amended) A prosthesis according to Claim 1 wherein the prosthesis
~~disc is composed of~~ includes a material that contains a ring of continuous fiber.

25. (Previously Presented) A prosthesis according to Claim 1 that contains
appendages to allow for physical attachment to the vertebral body and to prevent
dislodgement in situ.

26. (Currently Amended) A prosthesis according to Claim 1 wherein the prosthesis
body material is a monolithic cryogel.

27. (Withdrawn) A prosthesis according to Claim 1 wherein the material is a
composite material composed of more than one substance.

28. (Original) A prosthesis according to Claim 1 that is a permanent implantable
medical device.

29. (Currently Amended) A sterile prosthesis according to Claim 1 wherein the
prosthesis has a body that is manufactured as an oval or kidney shape for use as a total disc
replacement spinal disc prosthesis that substantially corresponds to a shape of a human spinal
disc and is devoid of endplates and allows motion between adjacent vertebrae, has exposed
fibers on the cranial and caudal surfaces thereof, ~~has a unitary and wherein the body is a non-~~
articulating solid monolithic cryogel body, ~~with the biocompatible elastomer having a~~
~~compressive modulus of elasticity between about 1.5MPa and about 10 MPa,~~ an ultimate
compressive and tensile strength greater than about 1 MPa, an ultimate tensile stretch greater
than about 15% in at least one direction, and comprises ~~fabrie~~ extensions from the body for
attachment to sides of a vertebrae.

30-33. (Canceled)

34. (Currently Amended) An implantable non-articulating total disc replacement spinal disc body having a superior surface and an inferior surface joined by a circumferential surface, the body defined by ~~comprised of a~~ solid biocompatible freeze-thaw hydrogel elastomer with a compressive modulus of elasticity less than about 100 megaPascals and an ultimate strength in tension greater than about 100 kiloPascals that exhibits the flexibility to allow at least 2 degrees of rotation between the superior and inferior faces with torsions of at least 0.01 N-m without failing.

35. (Previously Presented) The implantable spinal disc body of claim 34 wherein the implantable spinal disc superior and inferior surfaces are substantially that of a kidney corresponding to a human spinal intervertebral disc shape, shaped and formed by an extended oval surface and an indented surface, and wherein the cross-section of the implantable spinal disc is substantially rectangular.

36. (Original) The implantable spinal disc body of claim 34, wherein the periphery of the superior and inferior surfaces is substantially flat.

37. (Original) The implantable spinal disc body of claim 34, wherein the superior and inferior surfaces have a roughness index of between about 1 nm and about 2 mm in height.

38. (Original) The implantable spinal disc body of claim 37, wherein the circumferential surface has a roughness index of less than 1 mm.

39. (Original) The implantable spinal disc body of claim 34, wherein the implantable spinal disc body is at least partially surrounded by an attachment extension member having a

plurality of superior and inferior tabs connected to a band member for attachment of the implantable spinal disc to adjacent superior and inferior vertebral surfaces, respectively.

40. (Currently Amended) The implantable spinal disc body of claim 34, wherein the superior and inferior surfaces are covered with a surface treatment to promote attachment to adjacent vertebral bodies, and wherein the disc body is devoid of endplates and a plateless unitary body consists essentially of a monolithic defined by a freeze-thaw polyvinyl alcohol (PVA) hydrogel.

41. (Currently Amended) The implantable spinal disc body of claim 34, wherein the superior and inferior surfaces have ~~are provided with~~ a plurality of pores to promote tissue ingrowth.

42. (Previously Presented) The implantable spinal disc body of claim 34 wherein an anterior portion of the implantable spinal disc body is of greater thickness than a posterior portion.

43. (Currently Amended) An implantable spinal total disc replacement body consisting essentially of a biocompatible solid polyvinyl alcohol (PVA) cryogel elastomer material having [[a]] compressive modulus of elasticity that is less than about 100 megaPascals and an ultimate strength in tension greater than about 100 kiloPascals, the body having sufficient elasticity to allow for shock absorption and flexibility of motion between adjacent vertebrae, the body shaped to have comprising:

- a substantially concave superior surface having a substantially flat periphery surface;
- a substantially convex inferior surface having substantially flat periphery;
- the superior and inferior surfaces being joined by a circumferential surface; and
- the implantable spinal disc body being further characterized as being of a kidney shape formed by an extended oval surface and an indented portion, having a substantially

rectangular cross-section, and having an anterior portion of greater thickness than a posterior portion.

44. (Original) The implantable spinal disc body of claim 43 wherein the superior and inferior surfaces have a roughness index of between about 1 nm and about 2 mm in height and the circumferential surface has a roughness index of less than 1 mm.

45. (Currently Amended) The implantable spinal disc body of claim 43 further comprising:

an attachment extension band member at least partially surrounding the circumferential surface of the implantable spinal disc body; and

~~a plurality of~~ superior and inferior tabs extending from said attachment extension band member for attachment of the implantable spinal disc body to adjacent superior and inferior vertebral surfaces, respectively.

46. (Currently Amended) A prosthesis according to Claim ~~[[4]]~~ 43, wherein the device is a ~~plateless~~ non-articulating ~~unitary~~ body devoid of endplates.

47. (Currently Amended) The implantable spinal disc according to Claim 43, wherein the device has a non-articulating passively expandable monolithic ~~unitary~~ body of freeze-thaw cryogel that defines a core and annulus of the spinal disc implant.

48. (Currently Amended) An implantable spinal total disc replacement having a flexible ~~unitary~~ non-articulating solid body devoid of endplates, the ~~unitary~~ body having a nucleus and annulus that are both defined by a crystalline PVA hydrogel, the ~~unitary~~ body having a shape generally similar to that of a human spinal intervertebral disc with opposing top and bottom faces, wherein the crystalline PVA hydrogel has ~~a compressive modulus of elasticity that is between about 1 MegaPascal to about 20 MegaPascals~~, and an ultimate tensile and compressive strength of at least about 100 kiloPascals and exhibits sufficient

flexibility to allow at least 2 degrees of rotation between the top and bottom faces with torsions of at least 0.01 N-m without failing.

49. (Currently Amended) A disc according to Claim 48, further comprising a fabric band mesh ring attached to an axially extending circumferential surface of the ~~unitary~~ body.

50. (Currently Amended) A disc according to Claim 48, wherein the band mesh ring is molded to the axially extending circumferential surface of the body comprises a mesh fabric.

51. (Currently Amended) A disc according to Claim 48, further comprising a porous material attached to superior (top) and inferior (bottom) surfaces of the ~~unitary~~ body to allow for tissue ingrowth from adjacent vertebral tissue *in situ*.

52. (Currently Amended) A disc according to Claim 48, wherein the ~~unitary~~ body is configured to passively axially expand *in situ* ~~by at least about 10% over time.~~

53. (Withdrawn) A disc according to Claim 48, wherein the ~~unitary~~ body is configured to passively axially expand *in situ* between about ~~[[20]]~~ 5% to about ~~[[40]]~~ 600% over at least about 24 hours.

54. (Withdrawn) A disc according to Claim ~~[[53]]~~48, wherein the ~~unitary~~ body is configured to expand in height *ex vivo* about 50% over about 24 hours when placed in a bath of Normal saline.

55. (Withdrawn) A disc according to Claim 48, wherein the ~~unitary~~ body has anisotropic elasticity.

56. (Currently Amended) A disc according to Claim 48, wherein the ~~unitary~~ body is monolithic and has substantially the same durometer for locations proximate the nucleus and

the annulus.

57. (Currently Amended) A disc according to Claim 48, further comprising at least one inferior tab and at least one superior tab extending from the unitary body.

58. (Currently Amended) A disc according to Claim ~~[[52]]~~ 48, wherein the body is configured to passively expand, and wherein the body further comprises comprising a polyester fabric moldably attached thereto the upper and lower surfaces of the unitary body with appendages extending outwardly from the body for attaching the disc to sides of target vertebrae.

59. (Currently Amended) A disc according to Claim 48, wherein the disc body has the crystalline PVA hydrogel is devoid of structural reinforcement and is defined by a freeze-thaw PVA hydrogel a fabric covering molded into the disc body to extend beyond the disc body to define fabric appendages used to affix the disc body to target vertebrae.

60. (Currently Amended) A disc according to Claim 48, wherein the unitary body has ~~a compressive modulus of elasticity of at least about 2 MPa, and an ultimate strength in tension and compression of [[a]] at least about 1 MPa to thereby provide a relatively compliant body that has sufficient elasticity to allow flexible motion between vertebrae and act as a mechanical shock absorber.~~

61. (Currently Amended) A disc according to Claim 60, wherein the unitary body has a mechanical ultimate tensile strength in compression of at least about greater than 100 kiloPascals 10 MPa.

62. (Currently Amended) A disc according to Claim 48, ~~wherein the unitary body has opposing top and bottom faces, and wherein the unitary body can withstand between about 2-10 degrees of rotation between the top and bottom faces with torsions of between about 0.1~~

~~N-m to~~ greater than about 1 N-m.

63. (Currently Amended) A spinal total disc replacement prosthesis having a solid unitary body consisting essentially of a ~~non-reinforced~~ freeze-thaw PVA cryogel that defines a core and annulus, wherein the prosthesis body is non-articulating and has a ~~compressive modulus of elasticity that is less than 100 MegaPascals and greater than about 0.1 MegaPascals,~~ and an ultimate tensile strength that is greater than about 100 kiloPascals.

64. (Currently Amended) A spinal disc prosthesis according to Claim 63, wherein the unitary body is devoid of endplates and exhibits sufficient flexibility to allow at least 2 degrees of rotation between top and bottom faces of the body without failing with torsions of at least about 0.01 N-m~~has compressive modulus of elasticity that is between about 0.1 MegaPascal to about 10 MegaPascals.~~

65. (Currently Amended) A spinal disc prosthesis according to Claim 64, wherein the unitary body has an ultimate stretch in at least one direction of at least about 15%.

66. (Currently Amended) A spinal disc prosthesis according to Claim 63, wherein the body is unbounded on upper and lower surfaces to allow for axial expansion ~~of about 20%~~ when placed in a Normal saline solution for about 24 hours.

67. (Currently Amended) A spinal disc prosthesis according to Claim 63, ~~wherein the unitary body has opposing top and bottom faces, and~~ wherein the unitary body is configured to passively change size and can withstand at least about 2 degrees of rotation between the top and bottom faces with torsions of at least ~~about~~ 0.1 N-m without failing.

68. (Currently Amended) A spinal disc prosthesis according to Claim ~~[[67]]~~ 63, ~~wherein the unitary body can withstand between about 2 degrees to at least about 10 degrees of rotation between the top and bottom faces with torsions between about 0.1 N-m to about 1~~

N-m without failing wherein the body has an ultimate tensile stretch greater than 25 % in one direction.

69. (Previously Presented) A spinal disc prosthesis according to Claim 63, further comprising a fabric ~~non-metallic-mesh~~ sleeve on an axially extending surface thereof.

70. (Withdrawn) A spinal disc prosthesis according to Claim 63, wherein the ~~unitary~~ body has anisotropic elasticity.

71. (Currently Amended) A spinal disc prosthesis according to Claim 63, further comprising a plurality of axially extending tabs of that are attached to the ~~unitary~~ body and extend beyond upper and lower bounds of the ~~unitary~~ body in the axial direction.

72. (Previously Presented) A spinal disc prosthesis according to Claim 63, further comprising a mesh material disposed on at least one surface of the solid body.

73. (Currently Amended) A spinal disc prosthesis according to Claim ~~[[72]]~~ 63, further comprising a fabric molded to the solid body, wherein, in position, the fabric mesh material is affixed to vertebral bone.